REMARKS

The present application is directed to a method of detecting anti-tumor autoantibodies in an individual by detecting complexes formed by the binding of autoantibodies in a sample from the individual with tumor marker proteins isolated from a bodily fluid obtained from a body cavity or space in which a tumor is or was present or associated with in a cancer patient. Claims 9-10, 13-14, and 19-38 were previously cancelled and Claims 15-18 were previously withdrawn. Claims 1-8, 11, and 12 are currently under examination. By this amendment, Claim 1 is currently amended. No new matter is added.

Rejection under 35 U.S.C. §112, second paragraph

In the Final Office Action mailed December 21, 2007, the Examiner maintained the rejection of Claims 1-8, 11, and 12 under 35 U.S.C. §112, second paragraph. The Examiner stated that the claims do not describe whether the cancer patients from which the reagents are derived would also have the same or a similar cancer (such as stage or type) as the individual being tested. Applicants respectfully direct the Examiner to page 10, lines 15-19, of the specification, wherein it is stated that "an immunoassay reagent prepared from fluid and/or excretion taken from cancer patient(s) with a particular type of cancer may be used to assist in the diagnosis of the same types of cancers in other individuals." Furthermore, page 10, lines 24-29 of the specification also describes the situation where the immunoassay reagent could be prepared from a patient diagnosed with cancer, and then used in an assay "at a later date to assess the immune status of the same patient, for example to monitor disease progression and/or to assess the effectiveness of a course of anti-cancer treatment in that patient." One of ordinary skill in the art would understand that whether the cancer patients from which the reagents are derived would have the same or a similar cancer as the individual being tested would depend on the situation in which the claimed assay is being used. For example, the method could be used to characterize particular types or stages of cancer. However, the patient from which the sample is derived may also have a different cancer than the cancer that is to be diagnosed. See, for example, page 10 of the specification

("Samples may be pooled from two or more patients having the same or different stages of the same or different types of cancers."). In light of the above remarks, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

In the Final Office Action mailed December 21, 2007, the Examiner also stated that the meaning of the term "derived" was not clear. Applicants have amended Claim 1 to delete the word "derived", thereby rendering the rejection moot. In light of the above remarks, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Rejection under 35 U.S.C. §102(b)

In the Final Office Action mailed December 21, 2007, the Examiner maintained the rejection of Claims 1-7 under 35 U.S.C. §102(b) as anticipated by Hanash *et al.* (WO 00/26668, hereinafter "Hanash"). Applicants respectfully traverse.

Applicants respectfully submit that Hanash discusses assaying protein mixtures, including sera and other biological fluids that may contain S100 proteins, to determine the level of protein expression. In other words, the biological fluids are the **sample** being measured for S100 protein expression, not the **source** of the reagent that is being used to detect autoantibodies. Although Hanash discusses the detection of autoantibodies to S100 proteins, the Hanash paper never specifies that the S100 proteins used to detect the autoantibodies must be derived from a particular source. In fact, Hanash suggests that the S100 proteins may be obtained through recombinant DNA techniques (page 11, lines 22-31) or may be purified from natural sources, such as cells, using protein separation techniques well known in the art. This is in direct contrast to the method of the present application, which specifically states in Claim 1 that the tumour marker proteins **must** be from a particular source; namely, the sample being tested for autoantibodies is contacted with an immunoassay reagent, wherein the immunoassay reagent comprises one or more **tumor marker proteins prepared from a bodily fluid from a body cavity or space** in which a tumor is or was present or associated in one or more cancer patients. This is an important

distinction, because as stated on page 12, lines 11-18, of the specification of the present application, "the inventors have surprisingly observed that reagents prepared from tumour marker proteins isolated from body cavity-derived fluids or excretions from cancer patients…are generally more specific for cancer-associated autoantibodies than reagents based on the equivalent proteins isolated from 'normal' individuals." The specification, on page 12, lines 18-24, also states that because of this increased specificity, "immunoassays based on the use of reagents prepared from body cavity-derived fluids or excretion from cancer patients produce results that are more 'clinically relevant' in the detection of an immune response to cancer."

Hanash fails to acknowledge the significance of using tumor marker proteins that are obtained from a body cavity fluid or excretion of a cancer patient, and does not require the use of such tumor marker proteins in its methods for detecting autoantibodies. Claim 1 of the present application, on the other hand, requires the use of tumour marker proteins prepared from a bodily fluid from a body cavity or space in which a tumor is or was present or associated with in one or more cancer patients. Claims 2-7 directly depend on Claim 1 and, therefore, all require the use of such tumour marker proteins as well. Consequently, applicants respectfully submit that Hanash fails to anticipate the claimed method. In light of the above remarks, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

Double Patenting

In the Final Office Action mailed December 21, 2007, the Examiner maintained the provisional rejection of Claims 1-8, 11, and 12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 4, and 8 of copending Application No. 10/417,633 ("the '633 application") in view of Robertson *et al.* (WO 99/58978). Applicants respectfully submit that '633 application has not yet issued. Therefore, applicants wish to defer the filing of a terminal disclaimer in response to this rejection until allowable subject matter in the '633 application has been established.

In the Final Office Action mailed December 21, 2007, the Examiner maintained the provisional rejection of Claims 1-8, 11, and 12 on the ground of nonstatuory obviousness-type double patenting as being unpatentable over Claims 1, 4, 8, 19, 20, and 24 of copending Application No. 09/881,339 ("the '339 application") in view of Robertson *et al.* (WO 99/58978). Applicants respectfully submit that the '339 application was abandoned on March 17, 2004; consequently, the obviousness-type double patenting rejection is now moot.

CONCLUSION

The foregoing is submitted as a full and complete response to the rejections in the Final Office Action mailed December 21, 2007. No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Applicants assert that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case that may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned attorney is respectfully solicited.

Respectfully submitted,

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